K010129

APR - 5 2001

510(k) Summary

1. **DEVICE NAME:** Magnetic Resonance Diagnostic Device Accessory
**Model Number:** MRS-PRO
**Trade/Proprietary Name:** Proton Spectroscopy Package

2. **ESTABLISHMENT REGISTRATION:** 2020563

3. **U.S. AGENT NAME AND ADDRESS:**
Toshiba America Medical Systems, Inc.
2441 Michelle Drive, P.O. Box 2068
Tustin, CA 92781-2068

**CONTACT PERSON:**
Paul Biggins
(714) 730-5000, extension 7808

4. **MANUFACTURING SITE:**
Toshiba Corporation
1385 Shimoishigami
Otawara-shi, Tochigi-Ken
Japan 324

5. **DATE OF SUBMISSION:** January 12, 2001

6. **DEVICE DESCRIPTION:** The Proton Spectroscopy Package consists of software run on a separate workstation which allows analysis of proton spectroscopy data.

7. **SAFETY PARAMETERS:**

| | EXCELART™ MRT-1501/P3 |
|---|---|
| Maximum static field strength: | 1.5 Tesla |
| Rate of change of magnetic field: | 19.3T/second |
| Maximum radio frequency power deposition (SAR): | < 1.5 Watt/kg |
| Acoustic noise levels (maximum A weighted rms): | 95.0 dB |

Acoustic noise data was measured in accordance with NEMA guidelines.

8. **IMAGING PERFORMANCE PARAMETERS:**

| | | EXCELART™ |
|---|---|---|
| Specification volume: | Head: | 16cm dsv* |
| | Body: | 28cm dsv* |

* Same as previously cleared with initial EXCELART™ system (K990620).

9. **INTENDED USE**

| | |
|---|---|
| Anatomical regions: | Head |
| Nuclei excited: | Hydrogen |
| Diagnostic use: | Proton spectroscopy data acquisition and data processing |

10. **EQUIVALENCY INFORMATION:**
The Toshiba Proton Spectroscopy Package option is substantially equivalent to the Picker MR Spectroscopy Package (K991568). The software and workstation for the Toshiba Proton Spectroscopy Package are based on the current software and host computer previously cleared for the EXCELART™ with Pianissimo/P3 (K002531).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2001

Mr. Paul Biggins
Regulatory Affairs Manager
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
P.O. Box 2068
TUSTIN CA 92781-2068

Re: K010129
Proton Spectroscopy Package Model MRS-PRO
Dated: January 12, 2001
Received: January 16, 2001
Regulatory Class: II
21 CFR §892.1000/Procode: 90 LNI

Dear Mr. Biggins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K010129

Device Name: Proton Spectroscopy Package (MRS-PRO)

Indications for Use:

Imaging of:

The Toshiba Proton Spectroscopy Package is intended for use as a non-invasive diagnostic device that provides spectroscopy data acquisition and analysis of head anatomy. The spectroscopy data reflects NMR properties of proton density, spin-lattice relaxation, spin-spin relaxation, and flow velocity. The spectroscopy data may be useful in making a diagnosis when interpreted by a trained physician.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR§801.109)

(Optional Format 1-2-96)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010129